DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 25 1999

97N-0511 '99 MAR 16 A9:38

Mr. James S. Koch
Chief Executive Officer
Cliffstar Corporation
One Cliffstar Avenue
Dunkirk, New York 14048

Dear Mr. Koch:

Thank you for your letter of December 22, 1998 addressed to Representative Amory Houghton, regarding the Food and Drug Administration's (FDA or the Agency) proposal to ensure the safety of fruit and vegetable juices and juice products. Representative Houghton has asked us to respond directly to you. You noted that pasteurization is an effective method for eliminating pathogens in fruit juice and asked why FDA has proposed to require Hazard Analysis and Critical Control Points (HACCP) plans for all juice processors, even those who pasteurize their product.

As you are aware, HACCP is a science-based program that identifies the steps in food production where contamination is most likely to occur and then establishes preventive controls. Pasteurization is effective at controlling microbial contamination. A HACCP program, however, is a comprehensive system of hazard prevention and addresses chemical and physical hazards as well as microbiological hazards.

We have enclosed a news release that describes the HACCP proposal. We also have enclosed a copy of the Federal Register notice announcing the HACCP proposal for your information. It provides a detailed explanation of the information that led the Agency to propose this approach. As mentioned in the HACCP proposal, there were 10 recalls between 1990 and 1995 of fruit juice or beverages containing fruit juice because of the presence of food ingredients that were inadvertently added to the product, not declared on the label, or not suitable for the food. The proposal also notes cases of illness caused by juice products containing tin, lead, poisonous plant parts, or cleaning solution, as well as recalls of juice products due to improper sanitation procedures or faulty equipment. Pasteurization would not address these types of problems.

You are correct, however, that FDA's proposed rule was prompted primarily by concerns about microbiological contamination. As you are aware, FDA has documented significant public health hazards associated with fresh juice. For example, in

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October 1996, there was an outbreak of foodborne illness resulting from the contamination of fresh apple juice with Escherichia coli O157:H7. One child died, and at least 66 people became ill in this outbreak. In 1995, there was an outbreak of foodborne illness in Florida caused by Salmonella in unpasteurized orange juice. As a result of these and other outbreaks, FDA began to focus on the public health risks presented by fresh juices.

The Agency's proposed rule was the outgrowth of an extensive public process. FDA held a public meeting in December 1996 to exchange information on current industry practices and on developments in the science underlying the production of safe juices. FDA received and reviewed significant public comment from industry, trade organizations, consumers, consumer organizations, scientific/technical companies, academic institutions, State and local agencies, and Members of Congress. FDA also received advice from the Fresh Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods, a joint U.S. Department of Agriculture/FDA expert advisory group. The information FDA obtained indicated that new measures are necessary to ensure that juice is safe.

The virulence and increasing frequency of juice-associated outbreaks, and the risk of severe illness for vulnerable persons, created a need for prompt intervention. FDA subsequently announced in the Federal Register of August 28, 1997, the intent to establish a comprehensive program to address foodborne illness associated with the consumption of juice. The Agency's intent to propose a warning statement for unpasteurized or otherwise unprocessed juice and to propose HACCP requirements was announced in that notice, which requested comment.

On April 24, 1998, the two proposed rules were published in the Federal Register. Public comment on these proposals again was requested. FDA received substantial comments from the fresh juice industry. In promulgating the final warning statement rule, FDA reviewed and considered all pertinent public comments, including the information and recommendations from industry. The warning statement final rule was published on July 8, 1998.

FDA is continuing to evaluate the comments received on the HACCP proposal. These include extensive comments from the processed juice industry that make points similar to those in your letter; that is, FDA should focus this rulemaking on the 2 percent of the juice industry that does not pasteurize. No final action has been taken on that proposed rule, but these comments are clearly part of the administrative record.

We appreciate your interest in FDA's food safety programs. A copy of your correspondence has been forwarded to the Dockets Management Branch for inclusion in the record for the HACCP rulemaking. The comment period on this proposal closed August 7, 1998. While the Agency is under no legal obligation to consider comments submitted after the comment period, we do try to accommodate all comments as time and resources permit.

We hope this information is helpful.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

2 Enclosures
April 21, 1998 HHS NEWS
April 24, 1998 Federal Register Notice

cc: Dockets Management Branch (HFA-305)

The Honorable Amory Houghton
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Congress of the United States
House of Representatives

January 28, 1999

Jane E. Henney, M.D.
Deputy Commissioner
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20857

Dear Dr. Henney,

A constituent of mine has written to share his concern with proposed regulations that would affect his pasteurization operation (see enclosed). Would you kindly enter his concerns into the public comment on this regulation, and let us both know what the status of this issue is.

Many thanks.

All the best,

Amo Houghton

AH/cr
Enclosure
cc: James S. Koch

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December 22, 1998

The Honorable Amory Houghton
1110 Longworth House Office Building
United States House of Representatives
Washington, DC 20515

Dear Representative Houghton:

The purpose of this letter is to express my deep concern with respect to a regulation proposed by the U.S. Food and Drug Administration (FDA or Agency) and to request your assistance in having the regulation modified. If adopted, the regulation would adversely affect Cliffstar Corporation and its 550 employees in the 31st District.

On April 24, 1998 the FDA published a proposed rule entitled "Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice" (63 *Federal Register* [FR] 20450). Briefly stated, if adopted, the rule would impose an FDA-regulated HACCP regime on "any juice sold as such or used as an ingredient in beverages."

The Agency's proposal is a perfect example of the frequently cited "regulatory overkill." Mandatory HACCP for the entire juice industry is not warranted. The declared purpose of the proposed regulation is "to ensure the safe and sanitary processing of fruit and vegetable juices and juice products." The Agency has acknowledge that the major safety concern with juices is the possible presence of pathogenic microorganisms has stated that, "Pasteurization is an effective and proven technology to ensure that juice does not contain pathogens" (63 *FR* 20454).

The Agency has stated that less than 2 percent of juices are not pasteurized. Consequently, the companies producing the 98 percent of the products that are pasteurized will be regulated to force compliance on the negligent 2 percent. This raises the questions, "If pasteurization kills pathogens and only 2 percent of juices are not pasteurized, why not simply require all juices to be pasteurized?" Or, in the alternative, why not exempt from the proposed HACCP regime those companies that pasteurize the juice they produce.

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An industry-wide FDA-regulated HACCP program would place an undue burden on our company. The costs incurred by the implementation of such a program would not result in increased protection, and those costs would eventually be passed on to the consumer with no added value. Our industry presently is experiencing a decrease in sales. To add unneeded expense to our products would exacerbate an already serious problem.

We respectfully urge you to contact FDA Commissioner Jane E. Henney, M.D. and/or Joseph A. Levitt, the FDA's Director of the Center for Food Safety and Applied Nutrition, requesting them to delete the HACCP requirement for pasteurized juices and require pasteurization of all juices and juice products.

Sincerely,

CLIFFSTAR CORPORATION

James S. Koch
Chief Executive Officer

JSK/vp